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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/828,699

04/21/2004

Karen M. Cheves

1001.1705101

5388

28075 7590 01/02/2009  
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EXAMINER

GILBERT, ANDREW M

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

01/02/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/828,699	<b>Applicant(s)</b> CHEVES ET AL.	
	<b>Examiner</b> ANDREW M. GILBERT	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                         |                                                                             |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                                |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____                                                             | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Acknowledgements***

1. This office action is in response to the reply filed 10/3/08.
2. Claim 4 was cancelled. Claim 15 was amended.
3. Thus, claim 15 is pending for examination.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim 15 is rejected under 35 U.S.C. 102(e) as being anticipated by Grayzel et al (6942680). Grayzel et al discloses a cutting balloon catheter (10), comprising: an elongate catheter shaft (54); a balloon (14) coupled to the shaft, the balloon having a first inflated configuration and a second non-inflated configuration, wherein the balloon has a plurality of wings formed therein when in the second configuration (col 4, lns 1-6); a cutting blade (16) for severing or breaking up a lesion affixed to the balloon (col 3, lns 59-64; col 4, lns 12-22; col 6, lns 54-55, 61-65; col 7, lns 28-31), the cutting blade including means for cutting having two intersecting planes which form a cutting edge and means for gripping thereon and having a longitudinal axis (col 3, lns 59-64; col 4, lns 12-22; col 6, lns 54-55, 61-65; col 7, lns 28-31); wherein the means for cutting and

means for gripping are defined by a series of undulations (16) on the cutting blade; and wherein the undulations curve from side-to-side relative to the longitudinal axis (16; col 10; Figs 6a-10g). Additionally, see below in Response to Arguments.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vigil et al (5320634) in view of Parodi (5250070).

8. Vigil et al discloses a medical device, comprising: an elongate shaft (14) having a proximal end, a distal end, a first lumen (14) extending therethrough, and a second lumen (col 4, lns 63-64) extending therethrough; a balloon (12) coupled to the shaft, the balloon having a first inflated configuration and a second non-inflated configuration, wherein the balloon has a plurality of wings formed therein when in the second configuration (Fig 3b); and one or more cutting members affixed to the balloon (31), the one or more cutting members for severing or breaking up a lesion each having a longitudinal axis (Figs 3a, 4a-b), wherein the one or more cutting members each include a traction region that is configured to improve traction between the balloon and a target site (Figs 3a, 4a-b; and previous discussion of "traction region" in paragraphs 4-7 of the Final office action mailed on 11/1/2006). In reference to claim 15, Vigil et al additionally

discloses a cutting blade (31) affixed to the balloon (Fig 3a-b, 4a-b), the cutting blade including means for cutting having two intersecting planes which form a cutting edge and means for gripping thereon and having a longitudinal axis (Fig 3a-b, 4a-b).

9. However, Vigil et al fails to expressly disclose wherein the cutting member/blade has a traction region/cutting blade defined by a series of undulations curving from side to side relative to the longitudinal axis.

10. Parodi teaches that it is known to have the traction region/cutting blade defined by a series of undulations curving from side to side relative to the longitudinal axis (Fig 6c, summary, col 3, lns 2-col 4, lns 11) for the purpose of providing a nonskidding balloon surface that minimizes trauma to the whole endothelium (Summary, col 4, lns 3-11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the traction region as taught by Vigil et al with the traction region defined by a series of undulations curving from side to side relative to the longitudinal axis in the cutting members as taught by Parodi for the purpose of a nonskidding balloon surface that minimizes trauma to the whole endothelium (Summary, col 4, lns 3-11). Additionally, see Response to Arguments below.

### ***Response to Arguments***

11. Applicant's arguments filed 3/31/2008 have been fully considered but they are not persuasive.

12. The Applicant argues that:

- i. Grayzel does not disclose two intersecting planes that form a cutting edge; rather, the top surface appears to be flat or planar (e.g. Fig 9G, 9H. (Remarks, pg 3, paragraph 2)
- ii. Virgil and Parodi contradict each other and have no rational underpinning for their combination. Virgil has a sharp cutting blade and Parodi teaches lessening trauma to the arterial wall. (Remarks, pg 4, paragraph 4)

13. In response to the Applicant's arguments (i), the Examiner notes that top surface that appears flat or planar (e.g. Fig 9G, 9H) forms a plane that intersects the vertical side surface which also constitutes a plane. The two surfaces intersect and form a sharp edge that acts as a cutting edge. Grayzel still reads on the applicant's claim recitations.

14. In response to the Applicant's arguments (ii), the Examiner respectfully disagrees and believes there is sufficient motivation to combine. One of ordinary skill in the art would recognize the importance of cutting just lesions and plaques during treatment and attempting to minimize trauma to the endothelium wall. Parodi teaches that the undulating cutting members (Fig 6c) contact only a small part of the endothelium during angioplasty dilatation. Thus, in comparison to prior art balloons that contact the entire endothelium (Fig 5b) and flatten and destroy nearly all of the endothelium (Fig 5b) during angioplasty dilatation the ribs structured cutting members (6, Fig 6c) contact only 10% of the endothelium and only a small part of the endothelium (Fig 5c) is flattened and destroyed. These teachings of Parodi clearly indicate that the ribs (7) are

structured to cut and break up lesions during angioplasty dilatation treatment as shown in Fig 5c. The device of Parodi is fully capable of severing and cutting up lesions. Virgil discloses sharp cutting member with two intersecting planes forming the sharp cutting surface. There is sufficient motivation to modify the cutting member of Virgil with the undulating cutting member of Parodi. Furthermore, in addition to the teachings of the prior art references under KSR guidelines the modification is a simple substitution (MPEP 2141(III)(B)) of one straight cutting member for an undulating cutting member to obtain predictable results as taught by each reference, and, the modification would be obvious to try (MPEP 2141(III)(F)) to choose the undulating cutting member and try it out as a replacement for the straight cutting member as it is a choice of a finite number of identified cutting members that achieve a predictable solution with a reasonable expectation of success.

### ***Conclusion***

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/  
Examiner, Art Unit 3767  
**/Tatyana Zalukaeva/**



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***Supervisory Patent Examiner, Art Unit 3761***